



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,766	01/17/2002	Richard J. Fitzpatrick	1932.1110-001	5568

21005 7590 07/01/2005

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
----------	--------------

1618

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,766	FITZPATRICK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-34 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11-19 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 10, 20-24, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/30/05</u> . | 6) <input type="checkbox"/> Other: _____ |

28

Art Unit: 1618

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and IDS filed 03/31/05.

Examiner further acknowledges receipt of priority paper filed 04/25/05.

Priority

1. Receipt is acknowledged of papers filed under 35 U.S.C. 119 (b) based on an application filed in Chili. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

The filing date of the Chilean application is not disclosed in the communication and there was no prior acknowledgement of the foreign application. A new oath/declaration/application data sheet is required.

Oath/Declaration

2. In light of the foregoing regarding the foreign priority document filed 04/25/05, a new oath or declaration, which identifies the Chilean application as a foreign priority document and the filing date duly mentioned is required. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Art Unit: 1618

Request for Rejoinder of claims 9, 11-19 and 30-32 with the elected claims

The claims are not rejoined because the elected claims are not found allowable.

Applicants request to include claims 25-29 is persuasive and examination will be extended to claims 25-29 upon allowance of claim 1.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-3, 5 and 10 under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (US 4,217,429) is withdrawn in light of the amendment to the claims that recites treating oral mucositis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5,7,8,10, 20-24, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US 4,217,429) or Mandeville, III et al. (US 6,767,549) or Klofta et al. (US 6,238,682) or Drake et al. (US 5,419,897).

Each of the references cited above discloses use of ionene polymer to treat microbial infection or helminth infection as discussed in the previous Office action.

Wagner discloses the use of ionene polymer in treating antimicrobial infection (abstract; column 1, lines 22-26; columns 2 and 3). It is known that microbial infection causes

Art Unit: 1618

inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

Mandeville, III discloses treating microbial infection in a human mammal by administering therapeutically effective amount of a polymer that comprises an amino group or an ammonium group attached to the polymer backbone via an aliphatic spacer arm (abstract; column 2, lines 5-23; column 3, lines 45-67 and columns 4 and 5). Mandeville's polymer is an ionene. It is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

Klofta discloses application of a lotion that contains antimicrobial agent (abstract; column 4, lines 55-66) and ionene polymer (column 16, line 23) is listed as an antibacterial. It is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

Drake discloses the administration of an ionene polymer to treat helminth infections and infection causes inflammation (abstract). It is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

None of the references discloses treating oral mucositis. But compositions comprising ionene polymers are known in the prior art for treating infections that cause inflammations/mucositis. And the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

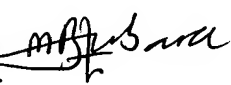
Art Unit: 1618

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ionene polymers of Wagner or Mandeville, III or Klofta or Drake to treat inflammations. One having ordinary skill in the art would have been motivated to treat infection with the expectation that the ionene polymers would be effective in treating inflammation resulting from infection as is disclosed by the prior art. And the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara 
Patent Examiner
Tech. Center 1600